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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,646	08/02/2001	Shinichi Ayabe	JKM-001	5225

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EXAMINER	
KALLIS, RUSSELL	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,646	AYABE ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,39,47-54,56,57,59,60 and 64-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *50 and 54* is/are allowed.

6)☒ Claim(s) *35,39,47,51,56,57,59,60 and 65-79* is/are rejected.

7)☒ Claim(s) *48,49,52,53 and 64* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-34, 36-38, 40-46, 55, 58 and 61-63 are canceled. Claims 69-79 are newly added. Claims 35, 39, 47-54, 56, 57, 59, 60 and 64-79 are pending and examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejection of Claims 61-63 under 35 U.S.C. 112, first paragraph, NEW MATTER is withdrawn in view of Applicant's arguments.

Rejection of Claims 35, 47-50, 60, 65 and 67 under 35 U.S.C. 102(b) is withdrawn in view of Applicant's amendments.

Claim Objections

Claims 35, 65, 67 and 76 are objected to because of the following informalities: Applicant's recitation of "in a sense direction" is objected to because "sense" is not a direction but rather refers to a strand. Both sense and antisense are transcribed in the 5' to 3' direction. Amending the claims to remove "in a sense direction" would obviate this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 69-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The added claimed material which is not supported by the original disclosure is as follows: Newly added Claims 69, 70 and 73 recite a naturally occurring sequence and a natural variant, while the specification only supports sequences and variants. Thus, the claims are drawn to NEW MATTER. Applicant is invited to point to the page and line number in the specification where support can be found. Absent of such support, Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 69-77, newly filed, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/30/2004. Applicant's arguments filed 9/28/2005 have been considered but are not deemed persuasive.

Applicant asserts that the recitation in the specification and in the claims of polynucleotides comprising variants of SEQ ID NO: 2 and polynucleotides having at least 95% homology to nucleotides 144-1712 of SEQ ID NO: 1 describes the broadly claimed genus because those recitations set forth structural features common to the members of the genus have the same length as SEQ ID NO: 2 or have at least 95% sequence identity to nucleotides 144-1712 of SEQ ID NO: 1 (response pages 8-10). This is not found persuasive because the claims are drawn to polynucleotides that have at least 70% sequence identity to nucleotides 144-1712 of

SEQ ID NO: 1 and encodes a polypeptide that retains 2-hydroxyisoflavanone synthase activity and are drawn to variants of SEQ ID NO: 2 comprising unspecified additions or deletions.

Applicant has not described any sequences that have unspecified additions or deletions to SEQ ID NO: 2 or have at least 70, 80 or 90% homology to nucleotides 144-1712 of SEQ ID NO: 1 and encode a polypeptide that retains 2-hydroxyisoflavanone synthase activity. Moreover those structural parameters namely the length of the polypeptide and the percent identity to SEQ ID NO: 1 encompass polypeptides or nucleotide sequences encoding polypeptides that have no 2-hydroxyisoflavanone synthase activity, and thus those structural features that applicant relies upon do not fulfill the written description requirement.

Accordingly, the specification fails to provide an adequate written description to support the genus of 2-hydroxyisoflavanone synthase encoding polynucleotides or hydroxyisoflavanone synthase polypeptide variants encompassed by percent identity of 90, 80 or 70% or the variant language as set forth in the claims comprising additions or deletions, or their complementary sequence as broadly claimed. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

Claims 35, 39, 47, 51, 56-57, 59-60, 65-68 remain and new Claims 69-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims drawn to the isolated polynucleotide of SEQ ID NO: 1 encoding the polypeptide of SEQ ID NO: 2 having 2-hydroxyisoflavanone activity and a method for producing 2-hydroxyisoflavanone synthase of SEQ ID NO: 2 by culturing a cell transformed with SEQ ID NO: 1, does not reasonably provide enablement for claims drawn to non-exemplified variants of SEQ ID NO: 2 that catalyze the synthesis of 2-hydroxyisoflavanone from flavanone; wherein the variant

comprises any non-exemplified protein that catalyzes the synthesis of 2-hydroxyisoflavanone from flavanone; or a non-exemplified protein having anywhere from 1 to 20 substitutions, deletions or additions to SEQ ID NO: 2; or 1 to 20 substitutions of any amino acid to SEQ ID NO: 2; or 1 to 20 substitutions to SEQ ID NO: 2 selected from the group consisting of between any one of Ala,Val, Leu and Ile, between Ser and Thr, between Asp and Glu, between Asn and Gln, between Lys and Arg and between Phe and Tyr; or for a polynucleotide complementary thereto; and non-exemplified polynucleotides encoding a 2-hydroxyisoflavanone synthase having at least 70% sequence identity to nucleotides 144-1712 of SEQ ID NO: 1 or a complement of said nucleic acid sequence, or a polynucleotide complementary thereto; and a method of producing a non-exemplified 2-hydroxyisoflavanone synthase in a host cell using any non-exemplified 2-hydroxyisoflavanone synthase coding sequence other than SEQ ID NO: 1 encoding SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/30/2004. Applicant's arguments filed 9/28/2005 have been considered but are not deemed persuasive.

Applicant asserts that one of skill in the art would have been able to make and use the broadly claimed polynucleotides encoding polypeptides having 2-hydroxyisoflavanone synthase activity, that one of ordinary skill in the art would have been able to make and use the invention as broadly claimed because making amino acid substitutions deletions and additions and testing for activity is a common practice in the art and would not require undue experimentation (response page 11). This is not found persuasive because the art does not recognize that 2-

hydroxyisoflavanone synthases are tolerant of modifications as broadly claimed absent further guidance. Applicant further asserts on page 11 of the response that substitution between SER and THR is taught in the specification and that the claimed polypeptide will retain the claimed functional properties. Clearly, the prio art cited (Sawada Y. *et al.*) does not support this conclusion, and thus the specificatiob provides inadequate guidance for making and using the broadly claimed genus of polynucleotides encoding polypeptides that have 2-hydroxyisoflavanone synthase activity.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified polynucleotide sequences encoding putative variant polypeptides of SEQ ID NO: 2 having substitutions, additions or deletions of 1 to 20 amino acids or substitutions selected from the group consisting of between any one of Ala,Val, Leu and Ile, between Ser and Thr, between Asp and Glu, between Asn and Gln, between Lys and Arg and between Phe and Tyr; or a polynucleotide complementary thereto; or non-exemplified polynucleotide sequences having at least 70, 80 or 90% sequence identity to the coding region of SEQ ID NO: 1 that also catalyze the synthesis of 2-hydroxyisoflavanone from flavanone, by producing expression vectors and testing for activity and 2-hydroxyisoflavanone product formation from flavanone, in order to identify those polynucleotides that when expressed in a host cell produce 2-hydroxyisoflavanone synthase.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation

would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

Claims 35, 39, 47, 51, 56-57, 59-60, 65-68 and 69-79 are rejected.

Claims 50 and 54 are allowed.

Claims 48-49, 52-53 and 64 are objected to for being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 35, 39, 47-54, 56, 57, 59, 60 and 64-79 are deemed free of the prior art given the failure of the prior art to teach or suggest a polynucleotide of SEQ ID NO: 1 encoding a 2-hydroxyisoflavanone synthase of SEQ ID NO: 2 and a method of culturing a host cell transformed with SEQ ID NO: 1 to produce a 2-hydroxyisoflavanone synthase of SEQ ID NO: 2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
December 19, 2005

RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER

Russell Kallis